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Opening Statement
Energy and Commerce Subcommittee on Health
Hearing on "Review of the Proposed Generic Drug and Biosimilars User Fees and Further Examination of Drug Shortages"
February 9, 2012

Today we will discuss two new user fee authorizations, one for generics and one for biosimilars, and also examine the worsening drug shortage problem facing our country.

Under the terms of the Generic Drug User Fee agreement that industry and FDA have negotiated, industry will pay approximately $1.5 billion over the next five years, in exchange for more efficient and predictable review of generic drug applications and increased inspections of drug facilities.

Currently, there are approximately 3,000 generic drug applications sitting in a backlog at FDA. One of the goals of the agreement is to eliminate this backlog within five years, speeding generic drugs to the patients who need them, without sacrificing quality or safety.

Another goal of the agreement is to have FDA inspect all drug facilities at an increased frequency and to bring parity between inspections of foreign and domestic facilities.

Industry and FDA have also negotiated a second user fee agreement, for biosimilars – those products approved under the abbreviated approval pathway for biological products shown to be highly similar to an FDA-licensed biological product.

This subcommittee has spent a great deal of time in the last few years trying to achieve a pathway to approval for biosimilars. This agreement authorizes four types of fees: application, product, establishment, and biosimilars product development, to make this a reality.

Finally, every day we are hearing from providers in our districts about increased difficulties in acquiring the drugs necessary to treat their patients. As this subcommittee looks to develop a package of ways to alleviate drug shortages, I look forward to hearing from our witnesses and learning their views on the matter.